REMARKS

In view of the foregoing amendments and following remarks responsive to the Office Action dated October 4, 2004, Applicant respectfully requests favorable reconsideration of this application.

Applicant respectfully thinks the Office for the indication that claims of 4-6 and 20 are merely objected to as depending from a rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The Office rejected claims 10 under 35 U.S.C. 112, first paragraph, as non-enabled. Applicant is hearing canceled claims 10, thus rendering this rejection moved.

The Office rejected claims 1-3, 7-19, and 21 under 35 USC 103(a) has been obvious over a Lenker in view of Fitz and further in view of Broome. Specifically, the Office asserted that Lenker discloses an apparatus and method for delivering a self-expanding stent-graft, the apparatus including an outer tube, an inner tube, the capturing element end of the runners/bent wires to a cyst delivering the stent-graft. The Office conceded that Lenker does not disclose the foldable sleeve or a blocking element as claimed, but asserted that Fitz discloses an apparatus for delivering a self-expanding stent including bent wires (42) and a foldable sleeve/restraining sheath disposed on the bent wires for delivering the stent as well as for capturing emboli. The Office further asserted that Broome discloses an apparatus for stent delivery including a bumper for preventing movement of the stent proximally when the outer sheath is retracted.

The Office concluded that it would have been obvious to modify Lenker's apparatus by employing a foldable sleeve/restraining sheath as disclosed by Fitz in order to deploy a self expanding stent in a vessel while preventing embolic migration using the foldable sleeve/restraining sheath and that it would have been obvious to employee bumpers as disclosed by Broome in the apparatus for preventing movement of the stent in a proximal direction when the outer sheath is retracted.

Applicant respectfully traverses.

The Present Invention

The present invention is a method and apparatus for delivering a stent into a body lumen. With reference to Figures 5 and 6, a stent delivery device in accordance with the present invention includes an outer tube 203 completely surrounding an inner tube 201. Slidably engaged on the inner tube 201 between the inner tube and the outer tube 203 is a carriage assembly 211 that includes a foldable sleeve 206 extending distally from the carriage assembly 211. The carriage also engages the outer tube so that movement of the outer tube can cause the carriage and sleeve to be drawn along with the outer tube causing the carriage to slide on the inner tube under force applied from the outer tube as described more fully below.

The carriage assembly 211 and sleeve 206 are designed to make it easy for a physician to insert a self-expanding stent 205 into the lumen between the inner tube 201 and the outer tube 203. Particularly, the sleeve is carried on the inner tube so that the inner tube can be positioned relative to the outer tube such that the sleeve extends beyond the distal end of the outer tube whereby the sleeve can be unfolded. The distal end 207b of the sleeve 206 is large enough to make it easy for a physician to insert an end of a self-expanding stent into the sleeve. Then, the inner tube can be drawn proximally so as to cause the sleeve to be drawn into the outer tube 203 and become folded between the inner tube and outer tube. Accordingly, the stent, having an end inserted in the sleeve, also is drawn into the outer tube, thereby capturing the stent in a radially-constricted condition within the lumen between the inner tube 201 and the outer tube 203. When the stent is ready for release, the outer tube 203 is drawn proximally relative to the inner tube 201.

Figures 8 and 9 illustrate two alternative designs that permit the outer tube 203 to apply a greater force to the carriage 211 than the frictional force between the carriage and the inner tube 201 so that the carriage 211 will be drawn proximally along with the outer tube 203 when the outer tube is drawn proximally, even though the carriage is frictionally engaged with the inner tube. Since the

carriage 211 is slidable on the inner tube and proximal of the blocking element, it will slide proximally on the inner tube 201 and be drawn proximally with the outer tube 203.

The Lenker Reference

The Lenker reference also discloses a method and apparatus for delivering a stent in a body lumen. However, it operates on an entirely different principle than does the present invention.

In Lenker, there are three tubes, namely, an outer tubular cover 32, a shaft or inner catheter body 34, and a core shaft 44. It is unclear from the rejection which of the three tubes the Office is considering to correspond to the outer tube claimed in the present application and which of the three tubes the Office is considering to correspond to the inner tube in the present invention. There are three possible permutations, namely, (1) the cover 32 corresponds to the claimed outer tube while the inner catheter body 34 corresponds to the claimed inner tube, (2) the cover 32 corresponds to the claimed outer tube while the core tube 44 corresponds to the claimed inner tube, or (3) the inner catheter body 34 corresponds to the claimed outer tube and the core shaft 44 corresponds to the claimed inner tube. None of these permutations meets the limitations of the claims.

The tubular cover 32 surrounds the shaft or inner catheter body 34. Cover 32 has a central lumen 36 within which the shaft 34 is slidably received. A plurality of runners 42 extend distally from the distal end of shaft 34. The runners 42 are fixedly attached to the end of shaft 34. Shaft 34 also has a lumen in which a core shaft 44 is slidably disposed. Core shaft 44 defines a guide wire lumen 46 within it. A graft 10 is radially compressed and restrained within the plurality of runners 42. In turn, cover 32 prevents runners 42 from expanding outwardly when the shaft 34 and runners 42 are drawn within the cover 32. In operation, a graft 10 is loaded into the distal end 40 of the cover 32 facilitated by the runners 42. As seen in Figure 3, extending shaft 34 distally so that runners 42 extend beyond the distal end of cover 32 allows runners 42 to flex outwardly.

The graft 10 may be inserted between the outwardly flexed runners and compressed by withdrawing the shaft 34 and runners 42 into the distal end of the cover 32. When it is time to release the graft, the cover 32 is retracted proximally relative to the shaft 34 and core shaft 44. As cover 32 is retracted, runners 42 retain their axial position, sliding over the inner surface of cover 32, thus allowing the graft 10 to expand. Shaft 34 may then be retracted proximally, drawing the runners 42 back within cover 32 thereby collapsing them.

Note the following key distinctions between the present invention and the delivery catheter of Lenker. In the present invention, the carriage with sleeve slidably engages the inner tube. In Lenker, the runners are bonded to the shaft 34. Thus, the runners 42 cannot slide relative to the shaft 34. Also note that runners 42 do not engage the core shaft 44 at all. Further, runners 42 are fingers extending from the distal end of shaft 34 and do not comprise a sleeve. Even further, there is no blocking element in Lenker. Lenker does have a distal force-imparting structure 67 bonded to the core shaft 44 and it serves the function of preventing the graft from moving proximally past a certain point (as does the blocking element at the present invention). However, unlike the blocking element of the present invention, it serves no function whatsoever with respect to preventing the runners 42 from moving distally past any particular point. In fact, the runners 42 and the shaft 34 to which it is bonded never come in contact with the force-imparting structure 67.

The Fitz Reference

Fitz discloses an apparatus and method for treating stenosed cerebral blood vessels and, particularly for deploying a self-expanding stent in a body vessel while preventing embolic migration. With reference to Figures 11-14, the system includes a catheter 62 with a self-expanding stent 66 mounted at its distal end and trapped within a restraining sheath 64 that is capable of both expanding and retracting. The restraining sheath 64 is forced open when it is in position and ready for deployment by an umbrella-like expansion structure 40, 42, 44 such as one of the three alternate structures shown in figures 1, 3, and 6 of Fitz.

The primary purpose of the sheath 64 and umbrella-like expansion mechanism is to cause the sheath to expand and seal off the body lumen 60 temporarily while the system generates a negative pressure that will break loose embolic material 72 and cause it to flow toward a filter 70 within the delivery apparatus. The sheath 64 prevents the embolic material 72 from getting around the delivery mechanism but instead traps the embolic material 72 between the sheath 64 and the catheter tube 62. The sheath can then be retracted into its radially constricted state, thereby trapping the embolic material between the tube 62 and the sheath 64. The delivery apparatus is then withdrawn, taking the embolic material 72 away with it.

In accordance with the disclosure of Fitz, the proximal end of the sheath as well as the proximal end of the expanding mechanism are fixed to the catheter. See, for instance, column 3, lines 41-43, column 3, lines 58-60, and column 4, lines 3-6.

Accordingly, not only does Fitz fail to disclose an outer tube as claimed, it also fails to disclose that the sheath is slidably engaged with said inner tube as claimed. Furthermore, it fails to disclose "a blocking element fixed to said inner tube near said distal end of said inner tube and adapted to block a stent inserted into said sleeve from becoming situated proximally of said blocking element and to block said capturing element from becoming situated distally of the predetermined point relative to said inner tube", as claimed.

The Broome Reference

Broome discloses a catheter that can be used to deliver a medical device such as a stent into a body lumen. The catheter comprises an inner lumen 104 and an outer lumen 102. A sheath 116 is disposed at the distal end of the outer lumen 102 that can surround the stent or other medical device to be deployed by the catheter. The sheath 116 is retracted by a mechanism comprising a pullwire 132 extending from the distal end of the outer lumen 102 that can be pulled to draw the sheath 116 proximally to release the stent or other medical device. The Office has cited Broome merely for its teaching of a bumper 160 located at

the distal end of the inner lumen 104 to block the stent or other medical device from being drawn proximally when the sheath 116 is drawn proximally to release the stent.

Applicant's Traversal

MPEP §2143 lists three requirements for a proper rejection based on obviousness, namely:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Office has improperly attempted to fashion an obviousness rejection from three disparate references that provide no suggestion of the proposed combination. Furthermore, the three references combined still fail to teach an important and fundamental limitation of the claims, namely, that the sleeve is slidably engaged on the inner tube and not fixed to it. In the present invention, this is a key feature because the sheath must be able to be drawn proximally along with the outer tube when the outer tube is drawn proximally relative to the inner tube in order to deploy the stent. This is not a concern for Lenker or Fitz because they operate on different principles and/or serve entirely different functions. As noted above, Lenker and Fitz operate on such different principles from the present invention that the runners (Lenker) and the sheath (Fitz), respectively, are fixed to the inner tube. They cannot slide relative to the inner tube.

Hence, neither reference discloses the limitation of claim 1 of "a capturing element comprising a foldable sleeve slidably engaged with said inner tube". With respect to Broome (which has not even been cited as being relevant to this issue in any event), Broome includes a sheath 116 can move relative to the inner lumen 104, but Broome has no component that could qualify as a outer tube

within which the sheath can be drawn. Also, Broome's sheath does not comprise a foldable sleeve, let alone one with a smaller proximal end than distal end.

Quite simply, no reference cited by the Office teaches the feature that is at the core of the present invention of a sheath that is slidable on an inner tube when it is drawn proximally by engagement with an outer tube when that outer tube is drawn proximally.

Accordingly, the rejection is faulty because it fails the most fundamental requirement of an obviousness rejection, i.e., that the references teach every limitation of the claim. None of the three references discloses the element of claim 1 that the capturing element having the sleeve slides on the inner tube.

However, even beyond this failure, the proposed combination is improper in any event because there is no reasonable suggestion of the proposed combination of the three references. Specifically, for starters, the proposed combination of Lenker and Fitz would require the artisan of ordinary skill to decide to incorporate the foldable sleeve of Fitz into the apparatus of Lenker while retaining the outer tube of Lenker. However, if one used the sleeve and sleeve deployment technique of Fitz, the outer tube of Lenker would be superfluous. The outer tube of Lenker would serve no function because Fitz's foldable sleeve and stent are retained in the constricted state by the sleeve itself and its deployment mechanism.

Thus, in order to arrive even at this intermediate step of the three way combination, the artisan of ordinary skill would need to decide to use both the outer tube of Lenker and the deployment mechanism of Fitz, However, this would make no sense because they both serve the same function. Alternately, this artisan would have to decide to use Fitz's sleeve but replace Fitz's sleeve deployment mechanism with the outer tube of Lenker. Clearly, this latter picking of Fitz's foldable sleeve while leaving behind its deployment mechanism cannot reasonably be said to be suggested by these two references. Such a picking and choosing between such closely related and interacting parts of Fitz that operate in conjunction to achieve the desired effect in Fitz would amount to invention and not be merely obvious.

Accordingly, the proposed combination necessary to even arrive at this intermediate step in the three way proposed combination of references is not fairly suggested by this prior art. When this is coupled with the aforementioned fact that, in addition, the references do not even disclose all of the limitations of claim 1, clearly leads one to conclude that the present invention is not obvious in view of these three references.

While the foregoing discussion focused exclusively on claim 1, it applies to all of the pending claims because claims 2-14 depend from claim 1 and therefore incorporate all of its limitations. Further, independent claim 15 is a method claim that incorporates all of the same basic distinctions over the prior art discussed above in connection with claim 1. All other pending claims, i.e., claims 16-21 depend from claim 15 and therefore distinguish over the prior art of record for at least all of these same reasons.

In addition, many of the dependent claims recite even further distinguishing features. For instance, claim 3 depends from claim 1 and recites that the capturing element comprises a "carriage at least substantially circumscribing said inner tube so as to be slidable longitudinally on said inner tube". As noted above, Fitz's sheath is fixedly attached to the inner tube, not slidably attached.

Claim 14 depends from claim 1 and recites that the capturing element "includes apertures for allowing fluids introduced between said outer tube and said inner tube to flow between said proximal end of said outer tube and said distal end of said outer tube". This is the exactly opposite to the purpose of Fitz. First, Fitz, of course, does not disclose an outer tube. However, even more fundamentally, the whole purpose of Fitz is to prevent the flow of fluids past the sheath. Thus, any assertion that it would be obvious to include an outer tube in Fitz and permit fluid to flow between the inner tube and outer tube would be directly contrary to the teachings on Fitz.

Claim 17 depends from claim 15 and adds that step 2 comprises "inserting said stent into said sleeve until an end of said stent abuts said blocking element". None of the references teach this. Broome is the only reference that discloses a

bumper and it does not disclose this step. The only function of the bumper disclosed in Broome is to prevent the stent from being drawn proximally during deployment.

In view of the foregoing amendments and remarks, this application is now in condition for allowance. Applicant respectfully requests the Examiner to issue a Notice of Allowance at the earliest possible date. The Examiner is invited to contact Applicant's undersigned counsel by telephone call in order to further the prosecution of this case in any way.

Respectfully submitted,

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